



AUG 01 2002

GE Medical Systems

K022310

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Submitter

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Waukesha, WI 53188 USA
Date Prepared: May 15, 2002.

PRODUCT IDENTIFICATION

Name: Advantage Windows X-Ray/MR Fusion

Classification Name: Accessory to X-Ray

Manufacturer : General Electric Medical Systems
283, rue de la Minière
78533 Buc Cedex, FRANCE

Distributor: General Electric Medical Systems, Buc, France.

Marketed Devices The X-Ray/MR Fusion is substantially equivalent to the devices listed below:

Model:	Advantage Windows Fusion (CT/MR Fusion)
Manufacturer:	General Electric Medical Systems, Milwaukee, WI
510(k) #:	K983256
Model:	Advantage Windows Fusion (CT/PET Fusion)
Manufacturer:	General Electric Medical Systems, Milwaukee, WI
510(k) #:	K010336

Device Description:

The GEMS Advantage Windows X-Ray/MR Fusion software package is an option on Advantage Windows that provides easy comparison of three dimensional (3D) images from X-ray angiography and Magnetic Resonance (MR). It allows 3D registration between two volumetric acquisitions, which may come from different acquisition modalities, producing fusion of angiographic and other anatomical images.

Indications for Use:

Advantage Windows /MR Fusion provides an easy means for comparison of three dimensional (3D) images from X-ray angiography (XR: providing anatomical imaging) and Magnetic Resonance (MR: providing anatomical imaging). It allows registration between two volumetric acquisitions, which may come from different acquisition modalities (XRay and MR), to help physicians in diagnostic radiology or therapy planning.

Comparison with Predicate:

The Advantage Windows X-Ray/MR Fusion option allows merged 3D registration of anatomical images from X-Ray with anatomical images from MR. The functional features of this package are substantially equivalent to that of the following devices:

Device Name	FDA Clearance Number
Advantage Windows Fusion	K983256
Advantage Windows CT/PET Fusion	K010336

Adverse Effects on Health:

The potential hazards are identified in a risk management summary (hazard analysis) and are controlled by:

- Software Development, Validation and Verification Process to ensure performance to specifications, Federal Regulations and user requirements.
- Adherence to industry and international standards.

Conclusions:

The Advantage Windows X-Ray/MR Fusion does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the Advantage Windows X-Ray/MR Fusion to be equivalent to those of Advantage Windows (CT/MR) Fusion (K983256) and Advantage Windows (CT/PET) Fusion (K010336).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 01 2002

General Electric Medical Systems
% Mr. Wolfram Gmelin
Technical Manager
TÜV Rheinland of North America
12 Commerce Road
NEWTON CT 06470

Re: K022310
Trade/Device Name: Advantage Windows X-ray/MR Fusion
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving
and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: July 16, 2002
Received: July 17, 2002

Dear Mr. Gmelin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

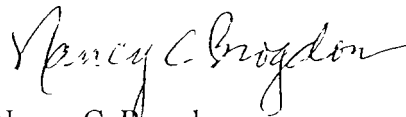
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure



General Electric Medical Systems

STATEMENT OF INTENDED USE

Device name: XR/MR Fusion

K022310

Intended Use:

Advantage Windows /MR Fusion provides an easy means for comparison of three dimensional (3D) images from X-ray angiography (XR: providing anatomical imaging) and Magnetic Resonance (MR: providing anatomical imaging). It allows registration between two volumetric acquisitions, which may come from different acquisition modalities (X-Ray and MR), to help physicians in diagnostic radiology or therapy planning.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ _____
(Per 21 CFR 801.109)

-OR-

Over-The-Counter Use _____

Nancy C. Bridson
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022310